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ARTICLE

TIGR® matrix surgical mesh – a two-year follow-up study and complication analysis in 65 immediate breast reconstructions

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ABSTRACT

In recent years, it has become increasingly popular to use matrices, such as acellular dermal matrices, in implant-based breast reconstruction. To lower the cost and to avoid implanting biological material, the use of synthetic meshes has been proposed. This is the first study examining TIGR® Mesh in a larger series of immediate breast reconstruction. The aims of the study were to examine complications and predictors for complications. All consecutive patients operated on with breast reconstruction with TIGR® Matrix Surgical Mesh and tissue expanders (TEs) or permanent implant between March 2015 and September 2016 in our department were prospectively included. Exclusion criteria were ongoing smoking, BMI (kg/m^2) > 30, planned postoperative radiation, and inability to leave informed consent. Fifteen breasts (23%) were affected by complications within 30 d: four (6.2%) major complications and eleven (17%) minor complications. The major complications included two implant losses and one pulmonary embolism (PE). Predictors for a complication were age over 51 years, BMI over 24.5 kg/m^2, large resection weight, and the need for a wise pattern excision of skin. Four minor surgical complications occurred after 30 d (minimum follow-up 17 months). There were no implant losses. In addition, minor aesthetic corrections, such as dog-ear resection, were performed in 10 breasts. In conclusion, breast reconstruction with a TE in combination with TIGR® Matrix Surgical Mesh can be performed with a low complication rate.

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KEYWORDS
Breast reconstruction; breast; ADM

Introduction

In recent years, it has become increasingly popular to use matrices, such as acellular dermal matrices, in implant-based breast reconstruction. Perceived advantages [1] of matrices include a better definition and control of the limitations of the implant pocket and the inframammary fold, and they enable a dual plane technique, which gives more naturally shaped lower breast pole and diminishes the need for lower pool muscular coverage and therefore extensive muscle dissection [2–4]. It has also been hypothesized that matrixes might decrease the risk of capsule formation [2,5]. The drawback of matrices is the possibly increased risk for complications, including infection, seroma formation, mastectomy flap necrosis and loss of implant [6,7]. In addition, the acellular dermal matrices are afflicted with non-negligible costs [8]. To lower the cost and to avoid implanting biological material, the use of synthetic meshes, such as polyglactin 910 mesh, has been proposed [9]. Nonetheless, little is known about the incidence of complications and results following mesh facilitated implant-based breast reconstruction.

TIGR® Matrix Surgical Mesh (Novus Scientific, Uppsala, Sweden) is a synthetic long-term absorbable mesh. It is macroporous and knitted from two types of fibers: a fast-degrading copolymer between glycolide and trimethylene carbonate and a slow-degrading copolymer between lactic and trimethylene carbonate. The slow-degrading part of the mesh keeps its strength for 6–9 months and is completely resorbed after about three years, whereas the fast-degrading part gives extra strength during the healing phase and gradually absorbs, making the mesh softer and more flexible and stretchable, during the first four months. Both parts of the mesh are degraded by hydrolysis into small molecules that are excreted from the body [10]. Several usages of TIGR® Mesh have been described; for instance, hernia surgery [11] and as a bra in implant-based breast reconstruction [12,13]. However, the published cases are few [12,13]. The cost of TIGR® Mesh is about one-third of the costs of ADM. This is the first study examining TIGR® Mesh in a larger series of immediate breast reconstruction.

The main aim of this study was to examine short-term complications (<30 d) following breast reconstruction with TIGR® Matrix Surgical Mesh in combination with a tissue expander or an implant. The secondary aim was to examine predictors for complications.

Patients and methods

All consecutive patients operated on with breast reconstruction with TIGR® Matrix Surgical Mesh and tissue expanders between March 2015 and September 2016 in our department were prospectively included in the study. Inclusion criteria were 18 years of age or older and indication for a uni- or bi-lateral mastectomy and immediate implant-based breast reconstruction because of oncological or prophylactic reasons. Exclusion criteria were ongoing smoking, BMI (kg/m^2) > 30, planned postoperative radiation, and inability to leave informed consent. If postoperative radiation was anticipated, the patient was excluded and recommended a delayed autologous reconstruction. Patients who previously had breast-conserving surgery and postoperative radiation

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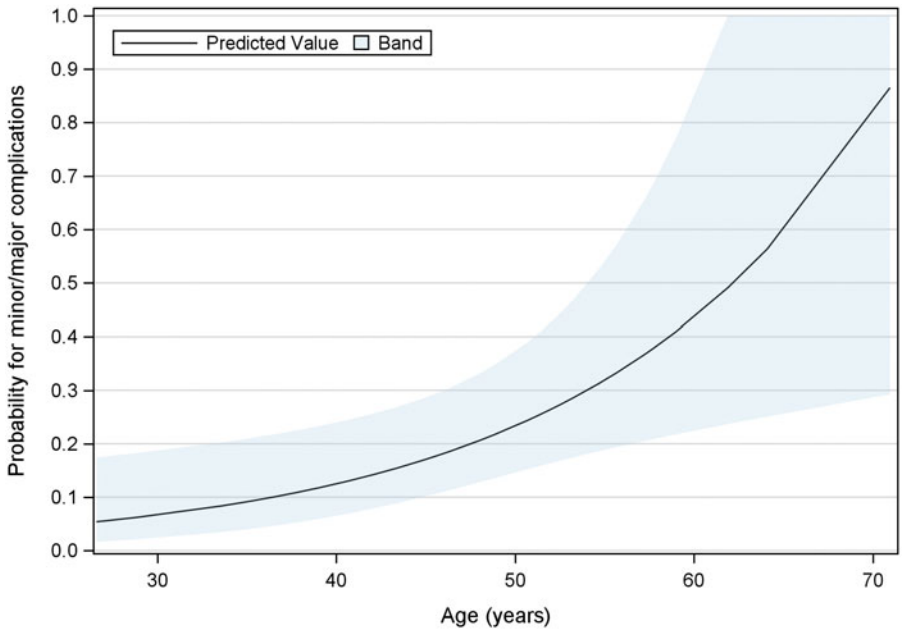

Figure 1. Circumvertical mastectomy with TIGR® Matrix Surgical Mesh sutured to m pectoralis major cranially and to the submammary fold inferiorly. Photo: Niclas Löfgren and Åsa Bell, Department of Plastic Surgery, Sahlgrenska University Hospital.

and were planned for an additional mastectomy due to an increased risk for breast cancer/a mutation were included. All patients were seen at a meeting diagnostic tool (MDT) conference before the operation. Procedures followed were in accordance with the Helsinki Declaration of 1964, as revised, and the Good Clinical Practice (GCP) guidelines.

Registered variables were age, preoperative body mass index (the ratio of the body mass in kilograms and the square of height in meters), smoking, comorbidities, laterality, reason for mastectomy, type of mastectomy, specimen weight, type and size of implant, perioperative inflation volume, and pre- or post-operative radiotherapy. Complications registered were based on previous studies [14] and included major complications: implant loss (including implant exposure, mesh exposure, implant loss and infection), mastectomy skin flap epidermolysis/necrosis requiring revision, NAC epidermolysis/necrosis requiring revision, thrombosis, and embolism; and minor complications: seroma requiring aspiration, hematoma requiring re-operation, and type IV delayed hypersensitivity reactions ('red breast'), epidermolysis not requiring revision, and minimal wound rupture/necrosis not requiring revision . Complications were classified as 'within 30 days' and 'after 30 days' of the immediate breast reconstruction.

Surgical technique

The patient was marked preoperatively in a sitting position. The anatomical boundaries of the breast as well as of the planned implant pocket and incision pattern were marked. If the breast were ptotic a wise pattern skin resection was made, otherwise a submammary incision was made. In cases where previous surgery had been performed modified skin patterns were used according to previous scars. A breast surgeon performed a nipple-sparing or skin-sparing mastectomy. Specimens were weight on scales and the weight registered with an accuracy of 0.01 kg. Then, a plastic surgeon performed the reconstruction. The inferior lateral and inferior attachment on the sternum of the pectoralis muscle were released, the muscle lifted and a retropectoral pocket created. The TIGR® Matrix Surgical Mesh (Novus Scientific, Uppsala, Sweden) was sutured in place to the inferior border of the pectoral muscle superiorly, the chest inferiorly and to the serratus fascia laterally, using 2–0 Maxon™ (Covidien, Dublin, Ireland) (Figure 1). A sizer was used to determine implant size and an anatomical tissue expander (TE) (CPX®, Mentor Worldwide LLC, CA) or a permanent anatomical silicone implant (direct-to implant (DTI)) (CPG®, Mentor Worldwide LLC, CA) was placed into the pocket. When a TE was used, it was partially inflated with saline, to the extent of achieving a tensionless closure. Two suction drains were used for each breast, one subpectoral and one subcutaneous. The drains were kept in place until the output was less than 30 ml per 24 h. Prophylactic perioperative and postoperative antibiotics (cloxacillin, or clindamycin in case of allergy) were given until the drains were removed. Amount of bleeding was estimated, by the anesthetist nurse, in milliliters based on blood in compresses. The patients were admitted to the hospital for 48 h postoperatively.

Follow-up

Patients were evaluated clinically one week and three months post-operatively, as well as during any TE fillings. In cases with TE, a second stage reconstruction with exchange for a permanent implant was planned when an adequate volume had been achieved. A clinical case report form (CRF) was used to ensure that all patients were evaluated for all studied complications in a standardized fashion. A final evaluation was performed 12–24 months after the initial operation.

Statistics

Numbers and percentages were given for categorical variables and means and standard deviations, and medians and ranges for continuous variables. Analyses were performed on breast level and not on patient level and therefore Generalized Estimating Equations (GEE) models were used for prediction of minor and major complications during the whole study and within first 30 d, adjusting for within-individual correlation with Poisson distribution and log-link function with robust error variances [15]. The analyses gave Risk-Ratios (RR) with 95% confidence intervals (CIs) and *p* values. Probability curves were drawn to illustrate statistically

significant predictors. All performed tests were two-tailed and a p value of .05 was considered to indicate a statistical significance. All analyses were performed with SAS software version 9.4 (SAS Institute Inc., Cary, NC).

Results

During the study period, 65 immediate breast reconstructions with TIGR® mesh were performed in 49 patients, 16 bilateral and 33 unilateral. Details about the patients and operations can be found in Table 1. Fifteen breasts (23%) were affected by complications within 30 d: four (6.2%) major complications and eleven (17%) minor complications (Table 2). The major complications included two implant losses and one pulmonary embolism (PE) and one reoperation due to hematoma in the same patient. The implant losses were due to wound dehiscence with exposure of the TE in one case and infection in the other case. The PE occurred despite prophylactic anticoagulation in a patient with an aortic valve replacement and an atrial fibrillation. The most common minor complication was epidermolysis not requiring revision, which occurred in three cases (4.6%). Risk factors (Table 3) for a complication were age over 51 years ($p = .0081$) (Figure 2), BMI over 24.5 kg/m^2 ($p = .051$) (Figure 3), large resection weight ($p = .0026$) (Figure 4), and the need for a wise pattern excision of skin ($p = .029$) (Figure 3). All patients, but one, have had their TEs exchanged for a permanent implant. During the operation the TIGR® meshes were visually well integrated (Figure 5) in all cases but one. Smoking was an exclusion criterion and could not be investigated in this material. A final control was performed in all cases, but two (97%). Minimum follow-up time was 17 months. Four surgical complications occurred after 30 d. Late complications included one case of wound dehiscence treated conservatively, one case of partial areola necrosis treated conservatively, and two cases of capsular contraction, Baker grade II, not requiring correction. There were no implant losses. In addition, minor aesthetic corrections, such as dog-ear resection and lipofilling because of wrinkles, were performed in 10 breasts.

Table 1. Details about the patients and the reconstructions.

		Total (patients = 49)
Age (years)		46.0 (9.4)
		45.6 (26.6–71.0)
Weight (kg)		65.0 (8.4)
		64.0 (49.0–84.0)
BMI (kg/m^2)		23.2 (2.6)
		23.1 (17.9–28.4)
Smoking	Yes	0
	No	49 (100.0%)
Bleeding (ml)		177.8 (231.9)
		100.0 (20.0–1450.0)
Follow-up time (months)		23.6 (6.1)
		23 (17–34)
		Total (breasts =65)
Indication		
	BRCA1	27 (41.5%)
	BRCA2	4 (6.2%)
	DCIS[a]	13 (20.0%)
	Invasive cancer	6 (9.2%)
	Increased risk[b]	15 (23.1%)
Type of mastectomy		
	Nipple sparing	57 (87.7%)
	Skin sparing	8 (12.3%)
Incision		
	Submammary fold	39 (61.9%)
	Wise pattern	11 (17.5%)
	Lateral	8 (12.7%)
	Vertical	3 (4.8%)
	Horizontal	2 (3.2%)
Postoperative radiation		0 (0%)[d]
Preoperative radiation		
	No	58 (89.2%)
	Yes[c]	7 (10.8%)
Resection weight (g)		264.4 (140.5)
		255.0 (50.0–660.0)
		$n = 62$
Type of implant		
	Expander	60 (92.3%)
	Permanent[e]	5 (7.7%)
Peroperative expander fill (ml)	Expander 0 ml	2 (3.5%)
	Expander >0 ml	53 (93.0%)
	Filled volume (ml)	142.2 (78.8)
		140.0 (20.0–350.0)
		$n = 53$

For categorical variables n (%) is presented.
For continuous variables Mean (SD)/Median (Min–Max).
[a]DCIS = ductal carcinoma *in situ*.
[b]In 14 cases a gene mutation could not be found, but the patients had an increased risk (>20–25%) for breast cancer according to BOADICEA (http://ccge.medschl.cam.ac.uk/boadicea/).
[c]One patient (two breasts) had had previous Mantle field radiation because of lymphoma. The other patients had a history of radiation following previous breast-conserving surgery prior to the mastectomy.
[d]All patients with anticipated postoperative radiation were excluded from study.
[e]One of the patients was reconstructed with permanent implant due to cosmetic implants *in situ* at the time of the mastectomy and the other four because of patient's preference.

Discussion

In modern implant-based breast reconstruction, matrices or meshes are often used to cover the implant and control the implant pocket [1]. An increased risk for complications has been reported in some studies [6,7]; nonetheless, little is known about the incidence of complications and results when synthetic matrices are used. This is the first study of complication rates in a larger series of immediate implant-based breast reconstruction using synthetic TIGR® Matrix Surgical Mesh.

The implant loss of 3.1% (2/65) seen in this study is similar to that of other studies on reconstruction with both biological [14,16] and synthetic matrices [9,17]. Other complications that might be higher in reconstructions with matrices include seroma formation and infections [7]. Previous reports have stated seroma formation in up to15% [7,18] of cases and infection in up to 30% [19]. In light of this, our seroma frequency of 3.1% and infection rate of 1.5% have to be considered low and speaking against an increased risk with TIGR® mesh. In brief, complication rates seem to be low with TE and TIGR® Matrix Surgical Mesh.

Our study revealed that predictors (Table 3) for complications are age over 51 years (Figure 1) and BMI over 24.5 kg/m^2

Table 2. Complications within 30 d.

Major complications	Total	4 (6.2%)
Breast-related (4.6%)	Implant loss	2 (3.1)
Other (1.5%)	Pulmonary embolism	1 (1.5%)
	Reoperation due to Hematoma	1 (1.5%)
Minor complications	Total	11 (17%)
	Epidermolysis[a]	3 (4.6)
	Hematoma[a]	1 (1.5%)
	'Red breast'	2 (3.1)
	Seroma	2 (3.1)
	Minimal wound rupture[a]	1 (1.5%)
	Partial necrosis[a]	1 (1.5%)
	Wound infection[a]	1 (1.5%)

For categorical variables n (%) is presented.
[a]Not requiring revision.

Table 3. Predictors for complications within 30 d.

			Minor/major complications within 30 d		
	Value	N Missing	*n* (%) Events	RR (95% CI)	*p* Value
Age (years)	≤37 years	0	0 (0.0)	–	–
	>37–45 years	–	4 (26.7)	–	–
	>45–51 years	–	2 (12.5)	–	–
	>51 years	–	7 (41.2)	1.06 (1.02–1.11)	.0081**
BMI (kg/m^2)	≤21.1 kg/m^2	0	1 (6.3)	–	–
	>21.1–23.0 kg/m^2	–	4 (22.2)	–	–
	>23.0–24.5 kg/m^2	–	3 (20.0)	–	–
	>24.5 kg/m^2	–	5 (31.3)	1.17 (1.00–1.38)	.051
Bleeding (ml)	≤75ml	2	4 (23.5)	–	–
	>75–125 ml	–	3 (20.0)	–	–
	>125–250 ml	–	2 (10.0)	–	–
	>250 ml	–	4 (36.4)	1.00 (1.00–1.00)	.88
Resection weight (g) (OR per 10 g increase)	≤142 g	3	0 (0.0)	–	–
	>142–255 g	–	4 (26.7)	–	–
	>255–361 g	–	4 (25.0)	–	–
	>361 g	–	5 (33.3)	1.04 (1.01–1.06)	.0026**
Preopreative radiation	No	0	11 (19.0)	–	–
	Yes	–	2 (28.6)	1.47 (0.32–6.82)	.62
Type of mastectomy	Nipple sparing	0	10 (17.5)	–	–
	Skin sparing	–	3 (37.5)	2.15 (0.74–6.29)	.16
Type of implant	Expander	0	11 (19.0)	–	–
	Permanent implant	–	2 (28.6)	1.45 (0.27–7.78)	.67
Incision	Submammary fold	0	6 (15.4)	–	–
	Wise pattern	–	5 (45.5)	3.07 (1.12–8.41)	.029*
	Other	–	2 (13.3)	0.93 (0.23–3.73)	.92

All tests are performed by using Generalized estimating equations (GEE) with modified poisson distribution with robust error variance, adjusting for within-individual correlation. For continuous variables, RR (95% CI) and *p* values are based on original values and not on stratified groups.
Stars (*) indicate level of statistical significance.

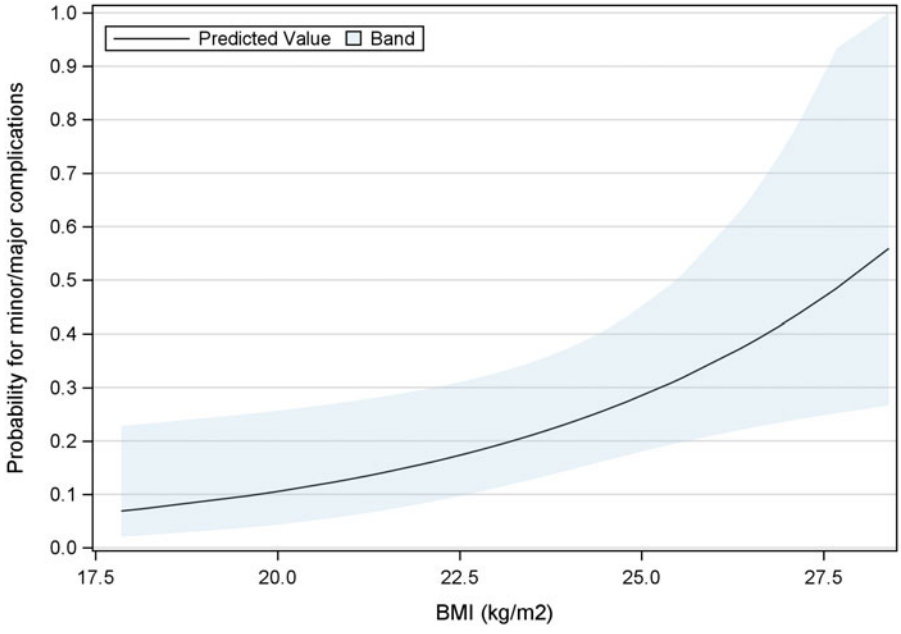

Figure 2. Probability for minor/major complications within first 30 d in study by age (years).

($p = .051$) (Figure 2), and indicators of large breasts, that is large resection weight ($p = .0026$) (Figure 3), and the need for a wise pattern excision of skin ($p = .029$) (Figure 3). The findings corroborate previous studies of risk factors for complications after immediate breast reconstruction with [14,16] and without matrices [20]. Nonetheless, the breasts in this series were relatively small, with a mean resection weight of 255 g. Breast volume was not a factor considered for inclusion or exclusion in the study and hence this is pure chance. The patients as a group had a relatively low BMI (23.1) and this could be one explanation for small resection volumes.

Previously, smoking [14,20] and permanent implant with a size if 600 cc or greater [14], also have been identified as a risk factor for complications. Smoking could not be investigated in this material as active smoking is considered a contraindication to immediate breast reconstruction in Sweden, and none of the patients were active smokers. There were few direct-to-implant reconstructions in the present material and it was not found to be

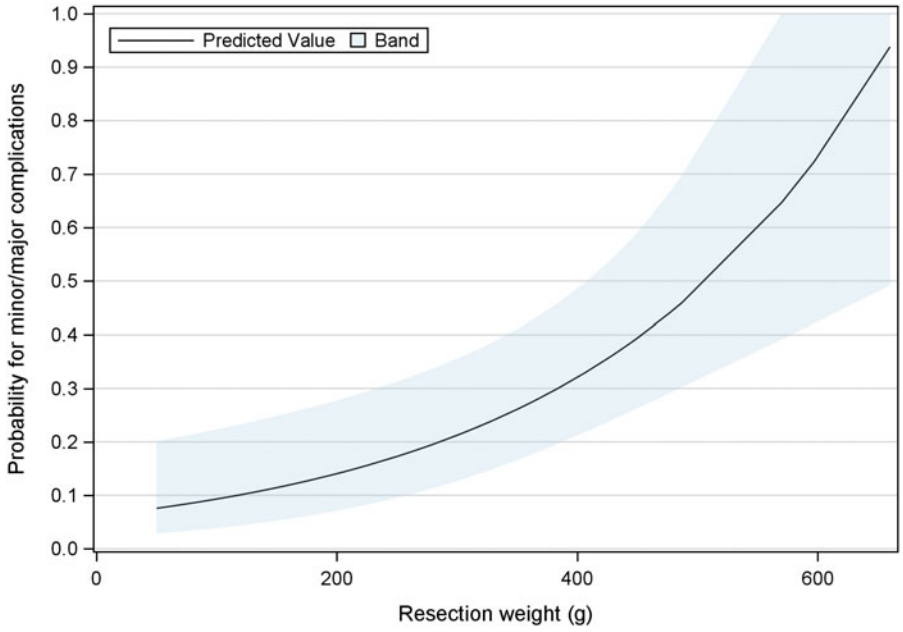

Figure 3. Probability for minor/major complications during the whole study by BMI (kg/m^2).

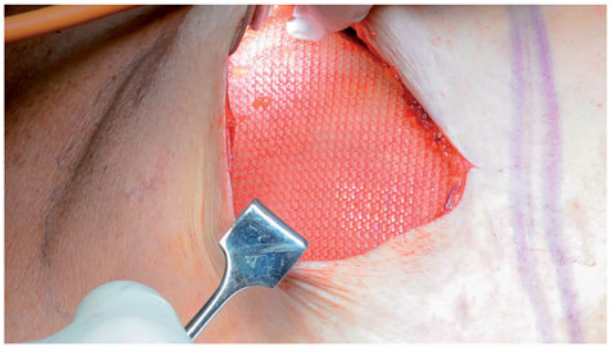

Figure 4. Probability for minor/major complications within first 30 d in study by resection weight (g).

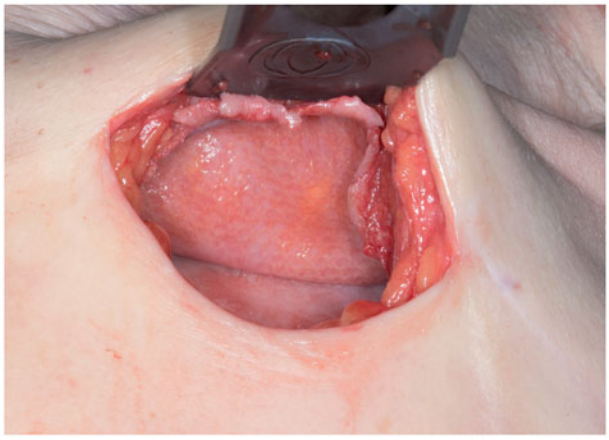

Figure 5. TIGR® Matrix Surgical Mesh at time of insertion (picture above). Well-integrated TIGR® Matrix Surgical Mesh when the TE was exchanged for a permanent implant about four months after the primary operation (picture below). Photo: Niclas Löfgren and Åsa Bell, Department of Plastic Surgery, Sahlgrenska University Hospital.

a risk factor (Table 3). Nonetheless, it is noteworthy that two of the five breasts reconstructed with permanent implants were affected with complications (Table 3). Similarly, two out of seven breasts treated with radiation preoperatively, another factor known to affect outcome in breast reconstruction [21], experienced complications. All patients who had received preoperative radiation had a previous history of breast cancer operated on with breast-conserving surgery and were now subject to an additional mastectomy because of a BRCA I/II mutation or an increased risk for developing breast cancer. The effect of postoperative radiation has not been investigated in this study due to our policy to recommend a delayed autologous reconstruction in these cases. There was a predominans of surgery for hereditary reasons compared to oncological reasons in this material. The reason for this is that there was a low referral rate of cancer patients with demand for immediate breast reconstruction from the breast cancer surgeons at the time for the study. However, we have no reason to believe that this has affected the results.

In summary, risk factors for short-term complications in implant-based reconstruction with TIGR® Matrix Surgical Mesh seem to be similar to those with reconstruction with other forms of matrices.

Little is known about possible long-term risks of biosynthetic meshes in breast reconstruction as the usage was first reported 2005 [23]. On the other hand, different forms of carbonate copolymers, such as Vicryl® and TIGR®, have been used in humans for many decades [23] and are known to be completely biodegradable, absorbable by hydrolysis, leaving no residues in the body. Therefore, synthetic meshes might be a safer choice in the long run.

It has been hypothesized that matrices might lower the incidence of capsule formation. Previous studies have suggested that when biological matrices are used capsular formation seems to be an early event and does not seem to progress over time [24]. The etiology of the reduction is thought to be that the matrices may function as a barrier to the patient's immune response to foreign bodies, that is, the implant [25,26]. However, there are no such histopathological studies on synthetic meshes used in breast reconstruction and hence nothing is known about the long-term potential of synthetic meshes to reduce capsular formation. Further, studies are needed to evaluate the possible long-term benefits of TIGR® Matrix Surgical Mesh.

In animal models, human acellular dermal matrices (AlloDerm® and Surgisis®) have shown better collagen deposition and organization, and neovascularization than synthetic matrices (Vicryl® mesh).

However, it is unknown if the described benefits of meshes in breast reconstruction, such as better definition and control of the limitations of the implant pocket [2–4], are actually dependent on collagen deposition and neovascularization, or a mere implant support during healing/capsule formation is enough. Better studies comparing long-term differences in aesthetic result, between synthetic and biological meshes, are needed to further explore if they have similar benefits.

In conclusion, breast reconstruction with a tissue expander and TIGR® Matrix Surgical Mesh can be performed with a low complication rate. The majority of the problems encountered after 30 days were minor aesthetic shortcomings. Further studies are needed to investigate the long-term complication rate, capsule formation and aesthetic result.

Disclosure statement

No potential conflict of interest was reported by the authors. There were no sponsors for the study.

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